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May 5, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Reference Docket No. 2004N-0133

Family Health International (FHI) wishes to submit the following comments and questions for discussion at the Agency's June 11, 2004 public meeting relating to the FDA's regulations and guidances on electronic records and electronic signatures in 21 CFR Part 11.

A. Part 11 Subpart A – General Provisions

Narrow Interpretation: FDA requested comments on whether part 11 should be revised to implement the narrow interpretation [scope] as described in the part 11 guidance document issued on September 5, 2003. FHI applauds FDA's narrowing of the scope and agrees that basing compliance requirements on predicate rule requirements is both reasonable and appropriate. However, the guidance indicates that FDA would generally not consider persons to be using electronic records in lieu of paper records when persons use computers to generate paper printouts of electronic records. While FHI agrees with this rationale, the guidance does not seem to consider the underlying reliability of that computer system in this particular regard. If such a computer system had not been appropriately validated then the printouts would be subject to some level of unreliability. Alternatively, if these paper printouts of the electronic records are generated by ad hoc queries to the clinical database, then a validated system does not assure the reliability of the paper printouts and some QA process would be needed for the reports themselves (in addition to knowing they were reporting on data stored in a validated system).

FHI encourages the FDA to clarify the level of reliability that would be expected to rely on paper printouts in such situations and also how expectations would differ for pre-programmed (or "canned") report printouts versus ad hoc printouts.

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Part 11 definitions: FDA requested comments on whether revisions to definitions in part 11 would help to clarify a narrow approach. In this regard FHI is seeking clarification on the definition of 'system' as used in part 11. 'System' could be broadly used to include hardware, software, documents, and all associated persons designing, validating, implementing, supporting, and using such systems; FHI seeks clarification of the definition of 'system' under the narrow scope of part 11.

B. Part 11 Subpart B – Electronic Records

Enforcement Action: The part 11 guidance identified four areas where the FDA does not intend to take enforcement action. These areas were identified as validation, audit trail, record retention, and record copying. FHI feels that the areas of validation and audit trails are of higher priority than that of record retention and record copying and by grouping them in this way we have a concern that the importance of validation and audit trails is minimized. FHI encourages the FDA to clarify this issue and what their expectations are in each of the four areas.

Open and closed systems: The FDA asked should part 11 continue to differentiate between open and closed systems and FHI feels that it should. Until appropriate controls exist to ensure access is limited to only authorized individuals, open systems are vulnerable and should be subject to stricter part 11 controls. FHI supports the FDA's differentiation between open and closed systems.

Audit trail safeguards: The FDA asked should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion and FHI concurs that part 11 systems should include such safeguards. In addition, FHI would encourage the FDA to specify that such safeguards should include appropriate change control procedures. To facilitate interpretation of part 11 FDA should provide more specific guidance and/or definitions of 'safeguards' that would meet with agency expectations. In particular, to specify any differences in expectations regarding audit trails for records versus audit trails for user log-in and access/authorization; it is not clear from the current guidance if the FDA regards the requirements for audit trails to be similar in both these different and distinct areas of compliance.

Legacy systems: The FDA has announced that they would exercise enforcement discretion with respect to all part 11 requirements for systems that otherwise were operational prior to August 20, 1997 (legacy systems). It is not clear from the part 11 regulation or subsequent guidance documents to what extent modifications could be made to such systems while retaining their legacy status. Clarification is sought in this area of the part 11 regulation and guidances.

Record conversion: It is not clear from the current regulation and guidances how part 11 applies to statistical analysis programs and data conversions. Clarification is required in these areas particularly with respect to agency expectations for change control procedures for data tables and analysis data sets (both in-production and post-production implementation). In particular, clarification is required when such data tables and analysis data sets are used to fulfill predicate rule requirements. Does the FDA view these tables and data sets as subject to part 11 under the narrower scope currently proposed?

Additional question: FHI seeks clarification on the responsibility for part 11 compliance at study investigative sites. FDA regulations and predicate rules defined in ICH GCP E6, define data integrity and quality as a sponsor responsibility primarily. In addition, study site investigators have a defined responsibility for data collection procedures, data quality, and data integrity. It is unclear in the part 11 regulation and guidance which party(ies) is ultimately responsibly for part 11 compliance as investigational sites and third-party CROs and FHI urges the FDA to clarify this important issue.

FHI trusts that our comments and questions will be fully considered and discussed at the public meeting on June 11, 2004. Should the FDA wish to discuss any of these comments or questions then do not hesitate to contact me as FHI is keen to facilitate discussion and dialogue on part 11.

Yours truly,

Janet Robinson

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